

REMARKS

Claims 1-57 are pending. Claims 1, 36 and 50-52 have been amended. Support for the amendments can be found throughout the application as filed. No new matter has been added.

Rejection of Claims 1-21 and 36 Under 35 U.S.C. §112, second paragraph

Claims 1-21 and 36 are rejected under 35 U.S.C. §112, second paragraph, "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention."

In particular, the Examiner asserts that "it is not clear what is meant by the terminology 'a cation from a salt' (claim 1)." The claims have been amended to recite "a salt comprising a monovalent or divalent cation", thereby obviating this rejection.

With regards to claim 36, the Examiner asserts that "it is not clear what is meant by the terminology 'calcium acetate pH 6.1'." Claim 36 has been amended to recite "calcium acetate having a pH of about 6.1", thereby obviating this rejection.

Rejection of Claims 1-3 and 5-57 Under 35 U.S.C. §112, first paragraph

Claims 22-57 are rejected under 35 U.S.C. §112, first paragraph, "because the specification, while being enabling for glycerol, does not reasonably provide enablement for polyhydric alcohol." Specifically, the Examiner asserts that "the terminology 'polyhydric alcohol' ... is not limited to an alcohol having any specific weight or chain length and therefore encompasses an alcohol having 100 or more carbon atoms. There is a good reason to doubt that such an alcohol will be useful in the claimed methods."

Applicants respectfully traverse this rejection. The claims are directed to methods of preparing and purifying a crystalline or crystal-like daptomycin that includes using a solution that includes a low molecular weight alcohol or polyhydric alcohol. The term "polyhydric alcohol" is defined at page 10, lines 4-5 as "compounds that contain more than one alcohol group, and less than eight carbons." Thus, contrary to the Examiner's assertions, polyhydric

alcohol as recited in the claims is limited to specific chain lengths, i.e., those having less than eight carbon atoms.

Applicants have clearly provided sufficient guidance that a skilled artisan could use a polyhydric alcohol in the claimed methods without undue experimentation. For example, at page 10, lines 5-7, Applicants provide examples of various polyhydric alcohols that can be used. In addition, throughout the examples, Applicants have used various polyhydric alcohols and have demonstrated that solutions that include these alcohols produce crystalline or crystal-like daptomycin. In view of the teachings in the specification, the use of a polyhydric alcohol (i.e., a compound having more than one alcohol group and less than eight carbon atoms) in the claimed methods has been enabled.

The Examiner further rejects claims 1-3 and 5-21 under 35 U.S.C. §112, first paragraph, "because the specification while being enabling for polyethylene glycol or polyethylene glycol monomethyl ether, does not reasonably provide enablement for an organic precipitant."

Specifically, the Examiner asserts that

the terminology 'an organic precipitant' encompasses a large number of organic compounds. Since the specification fails to provide any guidance as to how to choose the desired precipitants, it would take an undue amount of experimentation to determine which specific organic precipitant, with the exception of polyethylene glycol or polyethylene glycol monomethyl ether, will be useful in the instant invention

Applicants respectfully traverse this rejection. Contrary to the Examiner's assertion, the term "organic precipitant" is not a very large number of compounds. As above, this term is defined in the specification with guidance of what characteristics are needed to qualify as an organic precipitant. In view of such guidance, it would not require undue experimentation to practice the claimed invention.

For the reasons discussed above, Applicants respectfully request that the Examiner withdraw this rejection.


Applicant : Keith et al.
Serial No. : 10/024,701
Filed : December 17, 2001
Page : 12 of 12

Attorney's Docket No.: 13764-003001

Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: 5/21/04


Laurie Butler Lawrence
Reg. No. 46,593

Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110-2804
Telephone: (617) 542-5070
Facsimile: (617) 542-8906

20854996.doc